

This application is submitted in the name of the following inventor:

<u>Inventor</u>	<u>Citizenship</u>	<u>Residence City and State</u>
Brown, Stephen J.	United States	Woodside, California

The assignee is Health Hero Network, Inc., having an office at 2570 West El Camino Real, Suite 111, Mountain View CA 94040.

Title of the Invention

Treatment Regimen Compliance and Efficacy With Feedback

Related Applications

Inventions described herein can be used in combination or conjunction with inventions described in the following patent application(s):

- o Application Serial No. 09/20,323, Express Mail Mailing No. EE143637591US, filed November 30, 1998, in the name of Stephen J. Brown, titled "Leveraging Interaction with A Community of Individuals," assigned to the same assignee, attorney docket number HHN-007, and all pending cases claiming priority thereof.

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1   tient compliance can be relatively reduced even further. When the treatment regimen is  
2   relatively complex, some patients are even unable or unwilling to manage that treatment  
3   regimen.

4  
5           Known methods for monitoring and controlling treatment regimens are  
6   relatively costly and limited in capability. Some known methods are described in the  
7   following patents:

8  
9   o   U.S. Patent 5,408,443, "Programmable Medication Dispensing System," issued  
10   April 18, 1995 in the name of Edward D. Weinberger.

11  
12   o   U.S. Patent 5,642,731, "Method of and Apparatus for Monitoring the Management  
13   of Disease," issued July 1, 1997 in the name of Bruce A. Kehr.

14  
15   o   U.S. Patent 5,752,235, "Electronic Medication Monitoring and Dispensing  
16   Method," issued May 12, 1998 in the name of Bruce A. Kehr, et al.

17  
18           While these known methods generally achieve the goal of monitoring and  
19   controlling a treatment regimen, particularly a medication regimen, they suffer from sev-  
20   eral drawbacks and limitations.

1 First, there is a need to provide a portable system to monitor and encourage  
2 compliance, and facilitate data collection, so that patients are restricted as little as possi-  
3 ble regarding their activities and movements.

4  
5 Second, there is a need to determine if patients are actually complying with  
6 treatment regimens at times when the patients are relatively remote to client devices for  
7 the system. Known methods do not provide adequate feedback to determine whether pa-  
8 tients are complying with the treatment regimen unless they remain relatively local to cli-  
9 ent devices.

10  
11 Third, there is a need to determine whether treatment regimens have the de-  
12 sired and intended effects. Known methods do not provide adequate feedback to deter-  
13 mine whether treatment regimens are effective, or whether patients are suffering any un-  
14 toward side effects. Using known methods, medical personnel must generally wait for  
15 patients to complain, or for medical tests to show, that prescribed treatment regimens are  
16 inadequate or are producing side effects. Similarly, using known methods, patients un-  
17 dertaking non-prescribed treatment regimens generally do not have effective or conven-  
18 ient systems to monitor and record whether non-prescribed treatment regimens are pro-  
19 ducing intended results

20  
21 Fourth, there is a need to inform patients to follow treatment regimens, par-  
22 ticularly when patients are forgetful or treatment regimens are complex. Although known

1 methods do include reminders to patients, it would be advantageous to tailor those re-  
2 minders to patients' actual compliance history (thus, providing fewer reminders when they  
3 are relatively less necessary and more reminders when they are relatively more neces-  
4 sary).

5  
6 Fifth, there is a need to leverage expert knowledge to improve response to  
7 feedback from patients, and to reduce the time and expense required for medical person-  
8 nel to individually monitor, evaluate and modify treatment regimens.

9  
10 Sixth, there is a need to broaden application of reminder and expert knowl-  
11 edge leveraging systems beyond medication regimens, to include physical, psychological,  
12 self-improvement and other treatment regimens.

13  
14 Accordingly, it would be advantageous to provide a portable device that can  
15 be coupled and uncoupled to a communication system with feedback to monitor patient  
16 compliance with, and effectiveness of, treatment regimens, so that input from patients re-  
17 garding treatment regimens can be recorded, reviewed, analyzed and otherwise generally  
18 acted upon. Medical personnel and/or patients can thus (1) monitor compliance with  
19 treatment regimens, (2) monitor effectiveness or side effects of treatment regimens, (3)  
20 remind patients no more than necessary, and (4) possibly alter treatment regimens in re-  
21 sponse to feedback from patients. These advantages are achieved in embodiments of the  
22 invention in which a portable device is intermittently coupled to a client device in a cli-

ent-server system, the patient enters information to the portable device about following the treatment regimen while the portable device is uncoupled, and medical personnel or the patient can receive that information and possibly alter the behavior of the portable device when the portable device is re-coupled to the system.

### Summary of the Invention

The invention provides a method and system for interaction with a community of individuals, relating to compliance with and effectiveness of treatment regimens, including supply and use of pharmaceuticals, using a protocol or other intelligent message which acts in place of a service provider and which is capable of collecting or imparting information to patients in place thereof. Individuals interact with the protocol or intelligent message to provide assistance in all aspects of treatment regimen compliance, data collection, supply or delivery, review and modification. These aspects can include (1) reminders regarding compliance with a selected treatment regimen for medication, physical therapy, psychological therapy, self-improvement, or some combination thereof; (2) data collection of facts regarding patient compliance, symptomology, possible drug interactions or side effects of medication if required by the treatment regimen, and other facts relevant to evaluation and possible modification of the treatment regimen; (3) networked integration with workstations for medical professionals to automate approvals and modifications, and refills and delivery of medication if required by the treatment regimen.

1 A system includes a set of client devices and a server device. A service  
2 provider determines a treatment regimen for selected patients, determines a protocol to be  
3 followed by the client devices to assist the patient in complying with that treatment regi-  
4 men [in assisting with that medication regimen] and to maximize effectiveness of treat-  
5 ment, and sends that protocol to the server device. The server device can update (respon-  
6 sive to the protocol) selected instructions at the client devices, and can receive (respon-  
7 sive to selected instructions) information from the client devices regarding their associ-  
8 ated patients.

9  
10 In a first preferred embodiment, a client device, located locally to a patient,  
11 couples to a portable device (such as a cellular telephone, pager, "Palm Pilot" or other  
12 handheld computer, or watch), capable of being carried away by the patient to locations  
13 relatively remote from the client device. The client device can interact with the portable  
14 device: (1) to provide the portable device with the capability of reminding the patient re-  
15 garding the treatment regimen, or (2) to provide the portable device with the capability of  
16 further data collection regarding the patient. The client device can interact with the port-  
17 able device using a docking connection, an infrared connection, a radio-frequency con-  
18 nection, a plug-in connection, or another suitable connection.

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3 Brief Description of the Drawings

4

5 Figure 1 shows a block diagram of a system for interaction with a commu-  
6 nity of individuals to encourage and monitor compliance with a treatment regimen, using  
7 a protocol or other intelligent message which acts in place of a service provider to collect  
8 and impart information relevant to the treatment regimen.

9

10 Figure 2 shows a process flow diagram of a method for operating a system  
11 for interaction with a community of individuals to encourage and monitor compliance  
12 with a treatment regimen, using a protocol or other intelligent message which acts in  
13 place of a service provider to collect and impart information relevant to the treatment  
14 regimen.

15

16 Figure 3 shows a first preferred embodiment of a portable device used by  
17 the system to encourage and monitor compliance with a treatment regimen, and to collect  
18 and impart information relevant to the treatment regimen.

19



Detailed Description of the Preferred Embodiment

In the following description, a preferred embodiment of the invention is described with regard to preferred process steps and data structures. Embodiments of the invention can be implemented using general purpose processors or special purpose processors operating under program control, or other circuits, adapted to particular process steps and data structures described herein. Implementation of the process steps and data structures described herein would not require undue experimentation or further invention.

*System Elements*

Figure 1 shows a block diagram of a system 100 to encourage and monitor compliance with a treatment regimen using a protocol or other intelligent message which acts in place of a service provider to collect and impart information relevant to the treatment regimen, including a patient device 110, a pharmacist device 140, a medical professional device 150, and a server device 160, said devices being coupled using a communication network 130, and a portable device 112 which can be coupled to the patient device 110 to receive information regarding the treatment regimen and send feedback from the patient 111 responsive thereto.

For further information regarding a data structure and simplified patient interaction interface, and preferred embodiments of the patient device 110, pharmacist de-

1 vice 140, medical professional device 150, and the server device 160 including database  
2 161 of treatment regimen information, see related Application Serial No. 09/210,323, Ex-  
3 press Mail Mailing No. EE143637591US, filed November 30, 1998, in the name of Ste-  
4 phen J. Brown, titled "Leveraging Interaction with A Community of Individuals," as-  
5 signed to the same assignee, attorney docket number HHN-007, and other related appli-  
6 cations incorporated by reference therein.

7  
8 For further information regarding the protocol or other intelligent message  
9 used by the system, see related Application Serial No. 09/203,882, Express Mail Mailing  
10 No. EE143637565US, filed December 1, 1998, in the name of Stephen J. Brown, titled  
11 "Remote User Data Collection Protocols Including Data Structures and User Interface,"  
12 assigned to the same assignee, attorney docket number HHN-002, and other related appli-  
13 cations incorporated by reference therein.

14  
15 For further information regarding a medicine dispenser which can be used  
16 by the system, see related Application Serial No. 09/203,880, Express Mail Mailing No.  
17 EE143637557US, filed December 1, 1998, in the name of Stephen J. Brown, et al., titled  
18 "Using A Computer Communication System With Feedback to Dispense Medicine," as-  
19 signed to the same assignee, attorney docket number HHN-005, and other related appli-  
20 cations incorporated by reference therein.

1 *Portable Device*

2 Figure 3 shows a first preferred embodiment of a portable device 112 used  
3 by the system 100.

4  
5 In a first preferred embodiment, the portable device 112 includes a coupling  
6 element 113 for coupling the portable device 112 to the patient device 110, a memory  
7 element 114, a processor chip 115 including a clock circuit 116, a presentation element  
8 117, and a patient feedback input element 118.

9  
10 A service provider determines a treatment regimen for selected patients 111  
11 and a protocol to be followed by their portable devices 112 to assist the patients 111 in  
12 following the treatment regimen. The service provider sends the treatment regimen and  
13 protocol to the server device 160 where it is recorded in the database 161. The server de-  
14 vice 160 sends the treatment regimen and protocol information to the patient device 110,  
15 and optionally to the pharmacist device 140 and the medical professional device 150.

16  
17 The portable device 112 is coupled to the patient device 110 using the cou-  
18 pling element 113. The coupling element 113 may couple using a docking station, an in-  
19 frared connection, a radio-frequency connection, a plug-in connection, other suitable  
20 means or any variant thereof.

1 While coupled, the treatment regimen and protocol information received by  
2 the patient device 110 is sent to the portable device 112 and recorded in the memory 114.  
3 In a first preferred embodiment, the power source 119 is rechargeable and the charge can  
4 be replenished by the patient device 110 while the portable device 112 is coupled to it. In  
5 alternative embodiments, the power source 119 is rechargeable and the charge can be re-  
6 plenished by some other device, or includes one or more disposable batteries.

7  
8 After the treatment regimen and protocol information is recorded in the  
9 memory 114, the portable device 112 can be uncoupled from the patient device 110 and  
10 taken with the patient 110 to locations relatively or logically remote from the patient de-  
11 vice 110. Whether the portable device 112 coupled or uncoupled to the patient device  
12 110, when the patient 111 is due to perform an act according to the treatment regimen, the  
13 portable device 112 uses the presentation element 117 to provide a reminder message in-  
14 structing the patient 111 to perform that act. In a first preferred embodiment, the act to be  
15 performed is related to compliance with a medication regimen including, without limita-  
16 tion, obtaining medicine, taking medicine, taking medicine with another substance such  
17 as food or water, not taking medicine with another substance such as alcohol or incom-  
18 patible medications, or obtaining a prescription refill. In alternative embodiments, the act  
19 to be performed may be pursuant to a physical therapy regimen including, without limita-  
20 tion, exercising, stretching, changing position, or changing work routine; pursuant to a  
21 psychological therapy regimen including, without limitation, repeating an affirmation,  
22 meditation, self-hypnosis or other mental activity; or pursuant to a self-help regimen or

1 other type of treatment regimen such as weight loss including, without limitation, drink-  
2 ing water or eating a snack.

3  
4 The patient 111 performs the indicated act and enters a message into the  
5 portable device 112 confirming performance of the act using the patient feedback input  
6 element 118. Operation of the patient feedback input element 118 causes the processor  
7 chip 115 to cancel the reminder message, check the clock 116, and record the time and  
8 fact of performance in the memory 114. In a first preferred embodiment, the patient 111  
9 also enters additional information relevant to monitoring and evaluating the treatment  
10 regimen in response to queries by the presentation element 117 in accordance with the  
11 treatment regimen and protocol.

12  
13 The number of reminder messages provided to the patient 111, and the  
14 number of messages from the patient 111 confirming performance of the indicated acts  
15 and/or providing other information relevant to compliance with and effectiveness of the  
16 treatment regimen, is limited only by the memory capacity of the portable device 112.

17  
18 In a first preferred embodiment, the presentation element 117 is a human-  
19 readable visual display using LCD's, LED's, or other suitable devices. In alternative pre-  
20 ferred embodiments, the presentation element 117 can be a device which produces hu-  
21 man-intelligible sound, or a combination of devices which produce human-intelligible  
22 visual and audible signals.

1           At some later time, the portable device 112 is re-coupled to the patient de-  
2 vice 110 using the coupling element 113, causing the contents of the memory 114 to be  
3 downloaded into the patient device 110 and sent to the server device 160 for recording in  
4 the database 161. Such a time may be as is convenient to the patient 111, or according to  
5 a selected maximum time interval dictated by the treatment regimen and protocol, or as is  
6 required to replenish the power source 119 of the portable device 112, or in accordance  
7 with other requirements of the system 100.

8  
9           At the server device 160, the protocol or other intelligent message reviews  
10 and compares the information provided by the patient 111 to the requirements of the  
11 treatment regimen in order to evaluate the effectiveness of the treatment regimen towards  
12 achieving treatment objectives and as to compliance of the patient 111 with the treatment  
13 regimen. The protocol may then leave the treatment regimen unchanged or modify it as  
14 needed to increase effectiveness and/or compliance; in either case, the server device 160  
15 sends a message to the patient device 110 as to the regimen to be followed from that time  
16 forward. In a preferred embodiment, the server device 160 also sends that message to the  
17 pharmacist device 140 and the medical professional device 150. For additional informa-  
18 tion regarding the protocol used by the system 100 and interaction of the protocol with  
19 other elements of the system 100, see discussion above at *System Elements* regarding re-  
20 lated applications.

1 In a first preferred embodiment, information regarding the entire course of  
2 the treatment regimen, such as each updated regimen and its effectiveness and relative  
3 compliance by the patient can be stored by each of those devices and displayed on de-  
4 mand. In alternative embodiments, only the server records the entire course, or only se-  
5 lected devices, or some combination thereof.

6  
7 In a preferred embodiment, when a treatment regimen requires a patient 111  
8 to take one or more medications, the portable device 112 can be coupled to a medication  
9 dispenser containing medication specified by the treatment regimen. In an alternative  
10 embodiment, the portable device 112 also controls the medication dispenser so as to re-  
11 lease only the correct dosage of the correct medication at the correct time responsive to  
12 the treatment regimen. In a further alternative preferred embodiment, the dispenser  
13 automatically provides feedback to the portable device 112 when the correct medication  
14 is removed, canceling the reminder message and storing the feedback for subsequent  
15 downloading to the patient device 110 on the next occasion that the portable device 112 is  
16 coupled to the patient device 110.

17  
18 The patient device 110 can be any device for electronic communication in-  
19 cluding, but not limited to, an application specific device, a hard-wired telephone, a cel-  
20 lular telephone, a pager, a personal desktop computer, a personal notebook computer, a  
21 hand-held computing device, an internet appliance, an internet-enabled television such as  
22 WebTV, personal digital assistant such as the Palm III, or any variant thereof.

1 The portable device 112 can be any portable device for electronic commu-  
2 nication which is capable of being coupled to the patient device 110 including, without  
3 limitation, an application specific device, a cellular telephone, a pager, a personal note-  
4 book computer, a hand-held computing device, an internet appliance, a personal digital  
5 assistant such as the Palm III, a watch, or any variant thereof.

6  
7 The feedback input element 118 can be any means of providing input to an  
8 electronic communication device including, but not limited to, a button, a telephone key,  
9 a computer keyboard key, a voice-response activator, or any variant or combination  
10 thereof.

11  
12 *Method of Operation*

13  
14 Figure 2 shows a process flow diagram of a method for operating a system  
15 for leveraging expert interaction with a community of individuals to encourage compli-  
16 ance with a treatment regimen and for collecting and imparting information relevant to  
17 that treatment regimen.

18  
19 A method 200 is performed by the system 100, as follows:

20  
21 At a flow point 201, the system 100 is ready to proceed.



1 At a step 202, a service provider enters information concerning a treatment  
2 regimen and protocol to be followed by the patient 111.

3  
4 At a step 203, the treatment regimen and protocol information is sent to the  
5 server device 160 using the communications network 130.

6  
7 At a step 204, the server device 160 records the treatment regimen and  
8 protocol information received from the service provider in the database 161.

9  
10 At a step 205 in a preferred embodiment, the server device 160 sends the  
11 treatment regimen and protocol information to the patient device 110, the pharmacist de-  
12 vice 140 and the medical professional device 150 using the communication network 130.  
13 In alternative embodiments, the server device 160 may send the treatment regimen and  
14 protocol information only to the patient device 110.

15  
16 At a step 206, the portable device 112 is coupled to the patient device 110  
17 and the treatment regimen and protocol information is copied into the memory 114 of the  
18 portable device 112.

19  
20 At a step 207, the portable device 112 is uncoupled from the patient device  
21 110 and is taken with the patient 111 to a location relatively remote from the patient de-  
22 vice 110.

1 At a step 208, responsive to the treatment regimen and protocol information  
2 stored in the memory 114 in conjunction with input from the clock 116, the patient device  
3 110 uses the presentation element 117 to provide a reminder message to the patient 111  
4 that an act is required to be performed by the patient 111 and instructs the patient 111 re-  
5 garding the act to be performed.

6  
7 At a step 209, the patient 111 performs the indicated act as directed.

8  
9 At a step 210, the patient 111 operates the feedback input element 118 on  
10 the portable device 112, canceling the reminder message.

11  
12 At a step 211, the portable device 112 uses the presentation element 117 to  
13 query the patient 111 to provide information responsive to the protocol for evaluating the  
14 effectiveness of the treatment regimen.

15  
16 At a step 212, the patient 111 operates the feedback input element 117 to  
17 provide information responsive to the queries, and that information is recorded in the  
18 memory 114.

19  
20 At a step 213, the portable device 112 is re-coupled to the patient device  
21 110.

1           At a step 214, the information stored in the memory 114 is sent to the pa-  
2   tient device 110, which in turn sends that information to the server device 160 using the  
3   communication network 130.

4  
5           At a step 215, the information received by the server device 160 is recorded  
6   in the database 161.

7  
8           At a step 216, in a preferred embodiment the server device 160 sends the  
9   information received from the patient device 110 to the pharmacist device 140 and to the  
10   medical professional device 150 using the communication network 130. In an alternative  
11   embodiment, the server device 160 does not send the information received from the pa-  
12   tient device 110 to the pharmacist device 140 or to the medical professional device 150,  
13   whether using the communication network 130 or otherwise.

14  
15           At a step 217, the information received by the server device 160 from the  
16   patient device 110 is evaluated by the protocol.

17  
18           At a step 218, the protocol updates the treatment regimen and either leaves  
19   it unchanged or modifies it in accordance with the protocol logic.

20  
21           At a step 219 in a preferred embodiment, the server device 160 sends the  
22   updated treatment regimen information to the patient device 110, to the pharmacist device

1 140 and to the medical professional device 150, using the communication network 130.

2 In an alternative embodiment, the server device 160 does not sent the updated treatment  
3 regimen information to the pharmacist device 140 or the medical professional device 150.

4  
5 At a step 220 in a preferred embodiment, the pharmacist 141 and/or the  
6 medical professional 151 review and compare the original treatment regimen, the compli-  
7 ance and other information input by the patient 111, and the updated treatment regimen,  
8 and either leave the updated treatment regimen and protocol information unchanged or  
9 modify it as necessary. In an alternative embodiment, step 220 does not take place.

10  
11 At a step 221 in a preferred embodiment, the treatment regimen and proto-  
12 col information as unchanged or as modified by the pharmacist 141 and/or the medical  
13 professional 151 is sent to the server device 160 using the communication network 130.  
14 In an alternative embodiment, step 221 does not take place.

15  
16 At a step 222, the server device 160 records the treatment regimen and  
17 protocol information as unchanged or as modified by the pharmacist 141 and/or the medi-  
18 cal professional 151 in the database 161. In an alternative embodiment, step 222 does not  
19 take place.

20  
21 At a step 223 in a preferred embodiment, the server device 160 sends the  
22 treatment regimen and protocol information as unchanged or as modified by the pharma-

1 cist 141 and/or the medical professional 151 to the patient device 110 using the commu-  
2 nication network 130. In an alternative embodiment, step 223 does not take place.

3  
4 At a step 224, the patient device 110 sends the updated treatment regimen  
5 information to the portable device 112 and it is recorded in the memory 114.

6  
7 At a step 225, the patient device 110 replenishes the charge of the power  
8 source 119.

9  
10 At a step 226, the patient 111 uncouples the portable device 112 from the  
11 patient device 110.

12  
13 At a step 227, the pharmacist 141 provides a refill or new medicine to the  
14 patient 111 responsive to the treatment regimen and protocol information. In an alterna-  
15 tive embodiment, step 227 does not take place.

16  
17 *Alternative Embodiments*

18  
19 Although preferred embodiments are disclosed herein, many variations are  
20 possible which remain within the concept, scope, and spirit of the invention, and these  
21 variations would become clear to those skilled in the art after perusal of this application.